

4072582

MAY 30 2008

**Non-Confidential Summary of Safety and Effectiveness**

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12-May-08

Atos Medical AB  
Box 183 Tel – 011-46-415 198 00  
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**Official Contact:** Ferenc Dahnér – Regulatory Affairs Manager

**Proprietary or Trade Name:** Provox® Micron HME™

**Common/Usual Name:** HME and filter

**Classification Name/Code:** JOH – Tracheostomy tube and cuff (accessory)

**Device:** Provox® Micron HME™

**Predicate Devices:**  
Atos – Provox® HME system – K014102  
Atos – Provox® FreeHands HME – K022125  
In Health Blom Singer HME systems – K915786  
Draeger – Uni-Filter – K043120

**Device Description:**

The Provox® Micron HME™ is a device which covers the stoma of a laryngectomy patient. It is designed to heat and humidify inhaled air to reduce the drying out of the airway as well as it incorporates filter media to filter the inhaled air of bacteria, virus and particulate matter.

It also incorporates a feature whereby the user may close the device, diverting exhaled air through the esophagus to facilitate voicing. This feature is identical to the predicate, Provox® HME cassette (K014102) and Provox® FreeHands HME (K022125), the only difference between the proposed device and the predicates in the addition of filter media.

**Indications for Use:**

The Provox® Micron HME™ is a specialized stoma cover that acts as a heat and moisture exchanger (HME) and air filtration device for laryngectomized patients. Provox® Micron HME™ partially restores lost breathing resistance due to laryngectomy.

For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

It is intended to be used with the Provox® HME System.

Environments of use include – hospitals, sub-acute care institutions and home.

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**Patient Population:** For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

**Environment of Use:** Hospital, acute care settings, and home

**Contraindications:** None

**Summary of substantial equivalence**

Specification	Predicates	Proposed Device
<b>Indications for use</b>	<p>Is a heat and moisture exchanger (HME) that heats and humidifies inhaled air by retaining heat and moist(ure) from exhaled air in the device. (K014102 and K022125)</p> <p>Partially restores lost breathing resistance. (added) (K014102 and K022125)</p> <p>For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing. (K014102 and K022125)</p> <p>Provide filtered air whether the patient is in dry or humid surroundings, indoor or outside (K915786)</p> <p>Provide Filtration for reducing possible cross contamination including bacteria, viruses and dust (K043120)</p>	<p>The Provox® Micron Filter™ and HME is a specialized stoma cover that acts as a heat and moisture exchanger (HME) and air filtration device for laryngectomized patients.</p> <p>Provox® Micron HME™ partially restores lost breathing resistance due to laryngectomy.</p> <p>For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.</p>
<b>Environment of Use</b>	Hospital, sub-acute care settings, and home (K014102, K022125, K915786)	Identical

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Specification	Predicates Provox® HME Cassette (K014102) Provox® FreeHands HME (K022125) Blom Singer HME systems (K915786) Uni-filter (K043120)	Proposed Device
<b>Patient Population</b>	For patients with a voice prosthesis or surgical speech fistula in may also facilitate voicing. (K014102)	Identical
<b>Contraindications</b>	None	Identical
<b>HME function (Moisture loss) Per ISO 9360</b>	Yes 23.7 mg H <sub>2</sub> O / l (K014102)	Yes 22 mg H <sub>2</sub> O / l
<b>Filtration BFE/VFE Per ASTM F2101</b>	Yes No claims of BFE or VFE made indicated in literature (K915786) Filtration efficiency claims BFE – 99.98% Viral – 99.9% (K043120)	Yes BFE – >99.8% VFE – >99.8%
<b>Pressure drop (cm H<sub>2</sub>O)</b>	0.9 cm H <sub>2</sub> O @ 30 Lpm 2.11 cm H <sub>2</sub> O @ 60 Lpm (K014102)	0.7 cm H <sub>2</sub> O @ 30 Lpm 1.9 cm H <sub>2</sub> O @ 60 Lpm
<b>Used with Provox® HME system</b>	Yes (K014102)	Yes
<b>Materials</b>	Standard materials for HME and filters (K014102, K022125)	Yes
<b>Storage conditions</b>	15 to 25 °C (K014102)	Same

**Differences Between Other Legally Marketed Predicate Devices**

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY 30 2008**

Atos Medical AB  
C/O Mr. Paul Dryden  
President  
ProMedic, Incorporated  
24301 Woodsage Drive  
Bonita Springs, Florida 34134

Re: K072582

Trade/Device Name: Provox® Micron HME™  
Regulation Number: 21 CFR 868.5800  
Regulation Name: Tracheostomy Tube and Tube Cuff  
Regulatory Class: II  
Product Code: JOH  
Dated: May 12, 2008  
Received: May 13, 2008

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use Statement

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**510(k) Number:** K072582

**Device Name:** Provox® Micron HME™

### Indications for Use:

The Provox® Micron HME™ is a specialized stoma cover that acts as a heat and moisture exchanger (HME) and air filtration device for laryngectomized patients. Provox® Micron HME™ partially restores lost breathing resistance due to laryngectomy.

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Environments of use include – hospitals, sub-acute care institutions and home.

**Prescription Use XX**  
(Part 21 CFR 801 Subpart D)

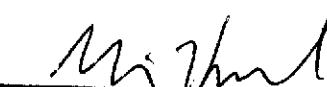
or

**Over-the-counter use**  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K072582